Supreme Court, U.S.
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No. ——— OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1994

DOROTHY MARIE REEVES,

Petitioner,

vs.

ACROMED CORPORATION
and
ST. PAUL FIRE & MARINE INSURANCE COMPANY,

Respondents.

PETITION FOR A WRIT OF CERTIORARI THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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QUESTIONS PRESENTED

I. Are damage claims for injuries caused by a medical device which was marketed for use in the spine in violation of federal medical device law preempted by 21 U.S.C. §360k(a) which provides "No state . . . may establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under" federal medical device law?

II. Are damage claims for spinal injuries caused by a medical device preempted by an FDA determination that the device was substantially equivalent to devices in commerce prior to May 28, 1976 particularly where the FDA determination was based on a fraudulent representation by defendant?

III. Are damage claims for injuries caused by a dangerous medical device preempted by 21 U.S.C. §360k(a) where FDA regulations implementing that provision expressly state that Section 360k(a) "does not preempt state or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices" and where the principles of state tort law on which plaintiff relies are general principles of law which apply to all products?

PARTIES TO THE PROCEEDING

All of the parties to this proceeding in the United States Court of Appeals for the Fifth Circuit are listed in the caption of the case.

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PETITION FOR A WRIT OF CERTIORARI THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Petitioner, Dorothy Marie Reeves, respectfully prays that a Writ of Certiorari issue to review the opinion and judgment of the United States Court of Appeals for the Fifth Circuit which was entered on February 10, 1995 insofar as it vacated the judgment of the District Court in favor of petitioner.

OPINIONS BELOW

The opinion and judgment of the United States Court of Appeals for the Fifth Circuit is officially reported as *Reeves v. AcroMed Corporation*, 44 F.3d 300 (5th Cir., 1995). It is set forth in the Appendix at A-1-A-19.

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals for which review is sought was issued and entered on February 10, 1995. (A-1 - A-19). A timely petition for rehearing was denied in an Order dated

April 3, 1995. (A-20). No Order was sought or granted extending the time within which any party might file a petition for a writ of certiorari. The instant Petition is filed within ninety days of the date on which the Court of Appeals denied the Petitioner's motion for rehearing. The jurisdiction of the Supreme Court is invoked pursuant to 28 *U.S.C.* §1254(1).

STATUTES AND REGULATIONS INVOLVED

The statutory provision relevant to this Petition is Section 521 of the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 *U.S.C.* §360k(a). Also relevant to this Petition is the FDA's preemption regulation, 21 *C.F.R.* §808.1. Additional FDA regulations which are relevant are the FDA's premarket notification regulations, 21 *C.F.R.* §807.87, the agency's prescription device labeling regulations, 21 *C.F.R.* §801.109, and the labeling correction regulations contained in 21 *C.F.R.* §895.25. The full text of the statute and each of these regulations is set forth in the Appendix to this Petition at A-21 through A-30.

STATEMENT OF THE CASE

A. The Regulatory Background

In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act in response to rapid technological changes in the medical device field and the perceived inadequacy of existing law to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." *S.Rep.No.* 33, 94th Cong., 2d Sess. 5, reprinted in 1976 *U.S.C.C.A.N.* 1070, 1075.

Under the statute, all medical devices are subject to certain "general controls" which relate principally to adulteration, misbranding, registration, record keeping, reporting, and good manufacturing practices. *See 21 U.S.C. §360c(a). See also, 21 U.S.C. §§351, 352, 360, 360f, 360h, 360i, and 360j.* Among the general controls provided by the statute is the requirement that adequate directions for use be supplied for any medical device. *21 U.S.C. §352(f).* In the case of prescription devices, FDA regulations state that this requirement is satisfied by la-

beling which contains all relevant information "under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented." *See 21 C.F.R. §801.109(c) & (d).* Another of the general controls applicable to all medical devices is the broad power conferred on the FDA to ban or restrict the sale of any medical device which it finds unreasonably dangerous. *See 21 U.S.C. §360f.* Pursuant to this grant of regulatory power, the agency has promulgated labeling correction regulations which set forth procedures by which the FDA may require labelling changes in order to reduce unreasonable health dangers. *21 C.F.R. §895.25.*

In addition, under the law the FDA is required to promulgate regulations classifying devices into one of three discrete categories. *See 21 U.S.C. §360c.* Class I devices are defined as those which generally pose little or no threat to public health and safety. *See 21 U.S.C. §360c (a)(1)(A).* This class includes devices such as tongue depressors, bedpans, crutches and elastic bandages. *See* 21 *C.F.R.* §§880.5075, 880.6230, 880.6730, 890.3150. Class II devices are those which are more complex than Class I devices and pose a greater risk to health. See 21 *U.S.C.* §360c(a)(1)(B). Examples include such items as oxygen masks, tampons and syringes. See 21 *C.F.R.* §§868.5580, 884.5470, 880.5570. Class III devices are those which "present a potential unreasonable risk of illness or injury." See 21 *U.S.C.* §360c(a)(1)(C).

Each type of device is subject to different degrees of regulation. Class I devices are subject to the "general controls" which apply to all medical devices. See 21 *U.S.C.* §360c(a)(1)(A). Class II devices may be subjected to "special controls" such as the promulgation of performance standards, postmarket surveillance, patient registries, and guidelines should the FDA determine, through regulatory action, that such controls are necessary to provide a reasonable assurance of safety and effectiveness for a specific device. See 21 *U.S.C.* §360c(a)(1)(B). Class III devices must receive premarket approval from the FDA. See 21 *U.S.C.* §360c(a)(1)(C) & 360e. By statute, the FDA may not grant premarket approval unless it determines that

there is a "reasonable assurance that such device is safe under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof." See 21 *U.S.C.* §360e(d)(2). To allow the FDA to make such a finding, its regulations require that an applicant for premarket approval furnish the agency with "copies of all proposed labeling for the device"[1] as well as product specifications, the intended use(s) of the device, manufacturing methods, and safety and efficacy data which typically includes data from controlled clinical trials conducted in accordance with protocols approved by the FDA.[2] See 21 *U.S.C.* §360e(c) & 21 *C.F.R.* §814.20.

The MDA draws a clear distinction between devices in commerce prior to its effective date, May 28, 1976, and new devices. Under the law, all devices which were in commerce prior to May 28, 1976, including Class III devices, may remain in commerce without further regulatory action by the FDA. See 21 *U.S.C.* §§360c(2)(C), 360c(f)(1), 360(k) & 21 *C.F.R.* §807.100. With respect to preamendment Class III devices, however, the FDA is obliged to develop and implement regulations requiring

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1. The FDA exercises considerable oversight with respect to the labeling content of devices which undergo the premarket approval process. *See 21 U.S.C. § 360e(d)(2)(A),(B),(D), 21 C.F.R. §814.44(d),(e); 21 C.F.R. §814.80; 21 C.F.R. §814.82(a)(3).*

2. If a manufacturer wishes to generate the scientific data necessary to obtain premarket approval and thereby market a Class III medical device, it may do so under the Investigation Device Exemption ("IDE") provisions of the Food, Drug and Cosmetic Act. *21 U.S.C. §360j (G) and 21 C.F.R. §813, et. seq.* These provisions authorize the FDA to grant an exemption permitting experimental devices to be used without premarket approval under stringent conditions established and actively supervised by the agency. *See 21 U.S.C. §360j(g)* and *21 C.F.R. §813 et seq.* The FDA may not grant an Investigational Device Exemption unless it makes a determination, akin to that required for premarket approval itself, that the device is sufficiently safe and effective when used in accordance with the protocols established by the agency to allow its experimental use on human beings. *Ibid.* When the FDA grants approval of an IDE, the device is considered an "investigational device." Under the FDA regulations the manufacturer or sponsor of an investigational device "shall not promote or test market an investigational device until after the FDA has approved the device for commercial distribution" outside of the IDE. See 21 *C.F.R.* §812.7(a).

that each preamendment Class III device receive premarket approval in the future as condition to its continued use in commerce. *21 U.S.C. §360c(b).*

With respect to new devices not in commerce prior to May 28, 1976, the MDA provides that such devices are Class III devices which may not be introduced into commerce without premarket approval unless the device is reclassified by the agency in response to a petition for reclassification or unless, pursuant to a premarket notification submitted by the proponent of the device in accordance with Section 510k of the statute, 21 *U.S.C.* §360(K), the FDA determines that it is "substantially equivalent" to a "predicate device." See 21 *U.S.C.* §§360c(2)(C), 360c(f)(1), 360(k) & 21 *C.F.R.* §807.100. A predicate device is one which was in commerce prior to May 28, 1976 or which was introduced thereafter and which was reclassified as a Class I or Class II device. *Id.* Under the law, a device is not "substantially equivalent" to a predicate device if it does not have the same intended use as a predicate device. *21 C.F.R. §807.100.* If the agency determines in response to a premarket notification that a product, as labeled, is substantially equivalent to a predicate device, then it may be legally marketed regardless of whether the predicate device is safe, effective or properly labeled.[3] Thus, as the FDA's own regulations explicitly state, a "clearance to market" decision pursuant to premarket notification "does not in any way denote official approval of the device" and it is misbranding to claim otherwise. See 21 *C.F.R.* §807.97.

Because the agency's function in acting on a premarket notification is simply to determine substantial equivalence and not the safety of a device as labeled, there is nothing in the agency's regulations which requires it to determine compliance

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3. *See Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273, 1282 (1992) (finding of substantial equivalence does not constitute device specific regulation of safety); House Committee on Energy and Commerce, *Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration Center for Devices and Radiological Health*, Report by the Subcommittee on Oversight

with general labeling regulations in making a clearance decision pursuant to a premarket notification. See 21 *C.F.R.* §§807.81, 801.100 and 895.25. Consistent with this, the premarket notification regulations do not require that the device proponent submit "all proposed labeling for the device" as required by the premarket approval regulations. Instead, the regulations simply direct that a premarket notification contain "proposed labels, labeling and advertisements sufficient to describe the device, its intended use and the directions for use." See 21 *C.F.R.* §807.87. These are required solely to enable the agency to make the substantial equivalence determination required in connection with premarket notification and not for the agency to make the kind of substantive determination of labeling sufficiency which is required in connection with an application for premarket approval. *See National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 998 (8th Cir. 1994).

Under the Medical Device Amendments, it is unlawful for any person to sell a Class III medical device which has not

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Footnote 3—Continued
and Investigations of the House Committee on Energy and Commerce, 103d Cong., 1st Sess. at 8-9 (Committee Print 103-N, GPO 1993)("Officials at the [FDA's] Center for Devices and Radiological Health point out that a finding of substantial equivalence does not represent, and should not be construed as, a statement of a device's safety and effectiveness. It means only that the device is substantially equivalent to a preamendment Class I, II or III device"); Department of Health and Human Services, Office of Inspector General, *Internal Control Weaknesses in the Food, Drug Administration's Medical Device 510(k) Review Process* 10-11 (No. A-15-89-00065 July 5, 1990)(510(k) process does not require submission of device specimen, verification of test results, or pre-marketing manufacturing inspections and "is not intended for determining premarket *approval*.") (emphasis in original); GAO, *Medical Devices; FDA's 510(k) Operations Could be Improved* 3 (PEMD-88-14 Aug. 1988) (same); Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J., 511, 516 (1988)("[S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective. The FDA must permit the later device to be sold.")

received premarket approval or which has not been cleared as substantially equivalent to an existing predicate device under the Section 510k premarket notification process. 21 *U.S.C.* §§360c(a)(1)(c), 360c(c), 360c(f)(1) & 360e; *Simon v. Ravenswood Hospital Medical Center*, 814 F.Supp. 33 (N.D. Ill. 1992); *United States v. An Article of Device*, 687 F.Supp. 990 (W.D. Mich. 1985). Moreover, it is unlawful for the supplier of any medical device to train physicians in any use of a device or to otherwise promote, market or label a device for any use other than those specific intended uses for which 510k clearance or premarket approval has been granted. 21 *U.S.C.* §§351(f), 352(a), & 352f(1).

B. Statement of the Facts

Defendant, AcroMed Corporation ("AcroMed") is a company which was formed to "manufacture and sell orthopedic devices, specifically spinal implants and instrumentation." (Tr., p. 68)[4]. In 1983 the company, through its principal director and stockholder, Arthur Steffe, M.D., developed and applied for a patent on a device which came to be known as the Variable Screw Placement ("VSP") Spinal Plate Fixation System. (Pl. Ex. #9; Tr., pp. 237-238). As described in the patent documents, this system consisted of slotted plates which were designed to be attached posteriorly along the vertical axis of the lumbar spine with bone screws inserted through the spinal "pedicles." (*Ibid.*) The pedicles are the thin bony archways which connect the vertebral bodies which are in front of the spinal cord with the posterior spinal elements which are located behind the cord. They are located in close proximity to the spinal cord and the nerve roots emanating from the cord. The VSP device was specifically designed for use as an adjunct to spinal "arthrodesis" or fusion surgery in which bone grafts are applied to permanently fuse two or more vertebrae. (Tr., pp. 312-314; 322-323).

The VSP Spinal Plate Fixation System represented a new approach to spinal fusion surgery. Indeed, prior to its introduc-

4. References to "Tr." in this Petition are to the Trial Transcript. References to "Pl. Ex. #" are to plaintiffs' Trial Exhibits.

tion, there were no American surgeons who were using screws in the spinal pedicles. (Tr., p. 316). Moreover, as AcroMed itself recognized, this new use raised significant safety concerns including the significant risk that screws would breach the pedicle walls on insertion causing permanent damage to the adjacent nerves and the risk that the tons per square inch of force which would necessarily be applied to the hardware elements by intervertebral movements prior to fusion might cause fracture of the hardware which, in turn, would damage surrounding nerves and blood vessels. (Tr., pp. 323, 342-343, 350). Despite these obvious risks, AcroMed never performed any animal, preclinical or clinical testing of its VSP device. (Tr., pp. 329-330).

AcroMed began selling the VSP device in early 1984 without filing a Section 510k premarket notification as required by federal law. (Tr., pp. 205-207, 237). On September 4, 1984 AcroMed sought to cure this violation by filing a 510k premarket notification for the VSP Spinal Plate Fixation Plating System (Pl. Ex. #12). This notification represented that the device was intended for use in spinal surgery. (*Ibid*). On December 19, 1984 the FDA responded to AcroMed's premarket notification. (Tr., pp 74-75; Pl. Ex. #13). In that response, the FDA informed AcroMed that it had determined that the VSP Spinal Plate Fixation System was not substantially equivalent to any device marketed in interstate commerce prior to May 28, 1976. (Tr., pp. 74-75; Pl. Ex. #13). Accordingly, the agency advised AcroMed that the device was a Class III device which could not be commercially distributed without receiving premarket approval. (*Ibid.*) The letter offered to re-evaluate the agency's determination in the event that AcroMed furnished additional information relating to the VSP device. (Pl. Ex. #13).

Following receipt of this letter, AcroMed ignored the FDA's admonition and continued to commercially distribute its VSP Spinal Plate Fixation System without applying for or obtaining premarket approval. (Tr., pp. 210, 212, 245).

On September 20, 1985 AcroMed filed another 510k premarket notification, supplying the FDA with additional information with respect to the VSP Spinal Plate Fixation System

and asking, once again, that the agency find the device substantially equivalent to pre-enactment devices. (Tr., p. 75; Pl. Ex. #14.) On December 15, 1985 the agency responded to the premarket notification as follows:

> "We have reviewed your Section 510(k) notification of intent to market the above device and we have determined that the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 or to any device which has been reclassified into Class I (general controls) or Class II (performance standards). This decision is based on the fact that there has not been an adequate demonstration that there was a preamendment device labeled, advertised or otherwise promoted with a design substantially equivalent to the VSP Spine Plate System and on the fact that it poses potential risks not exhibited by other spinal fixation systems, such as:
>
> (1) greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;
>
> (2) pedicle fracture during placement of screw;
>
> (3) soft tissue damage or inadequate fusion due to bending or fracture of device components; and
>
> (4) greater risk of pseudoarthrosis due to instability of design.
>
> Therefore, your device is classified by statute in Class III (premarket approval) under Section 513(f) of the Federal Food Drug and Cosmetic Act ("Act").
>
> Section 515(a)(2) of the Act requires Class III devices to have an approved premarket approval application before they can be legally marketed unless the device has been reclassified." (Tr., pp. 81-82; Pl. Ex. #15).

AcroMed was unwilling to accept this determination and sought to circumvent it. On December 20 and December 30, 1985, respectively, AcroMed submitted two separate 510k pre-

market notifications for the plate and screw components of the VSP system. (Tr., pp. 87-88; Pl. Ex. #s 16 & 17.). In these premarket notifications, AcroMed omitted all reference to the use of the device in the spine and referred to the device components as "nested bone plates" and "cancellous bone screws." (*Ibid.*) The notifications represented to the FDA that the device components were substantially equivalent to pre-amendment Class II devices used in the repair of arm and leg fractures and affirmatively stated that "there is no new application, indication, material, device configuration or specification presented" by the device components. (*Ibid.*) Finally, the premarket notifications did not contain any proposed labeling which disclosed the indications and contraindications to use, appropriate methods for use, and potential risks for the devices. (*Ibid.*)

Noting the fact that the nested bone plates and cancellous bone screws which AcroMed sought to market pursuant to the December, 1985 premarket notifications were identical to the components of the VSP Spinal Plate Fixation System which the FDA previously refused to clear for market, the FDA sought clarification from AcroMed concerning the intended use of the bone plates and bone screws which were the subject of the December, 1985 premarket notifications. (Tr., pp. 92-93, 127; Pl. Ex. #18.) On January 10, 1986 a representative of AcroMed responded to this request, affirmatively representing to the FDA that:

> "the proposed indications for use of the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for purposes of this 510k) the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates." (Tr., pp. 92-93.)

Based on this express representation, the FDA determined in February, 1986 that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices mar-

keted in interstate commerce prior to May 28, 1976 for the intended use represented by AcroMed. (Deft's Ex. #15). In making this determination, the FDA expressly cautioned AcroMed that the determination "does not in any way denote official FDA approval of your device or its labeling." (*Ibid.*). The device was classified as a Class II device for the use represented by AcroMed pursuant to *21 C.F.R. §888.3030.*

In January of 1986, AcroMed also applied for an IDE in order to conduct clinical trials of the VSP device in the human spine. (Pl. Ex. #s 18 & 19). In its IDE application, AcroMed represented that the trials would involve only ten hospitals and would be limited to 250 patients. *(Ibid).* AcroMed acknowledged to the FDA that spinal application of the VSP device was "experimental" and affirmatively represented that the device would not be employed in spinal procedures on any patients other than the 250 patients participating in the IDE study. (Pl. Ex. #16; Tr., pp. 214-215).

The representations which AcroMed made to the FDA concerning the intended use of its "bone plates" and "bone screws" were plainly false and misleading. At the trial of this matter, each of the representatives who testified on behalf of AcroMed conceded that the company's bone plates and bone screws were designed and developed specifically for use in treating spinal pathology and not for use in repairing long bone fractures as AcroMed told the FDA. (Tr., pp. 69, 212-213, 229, 231, 238, 344).

Consistent with this, AcroMed marketed its VSP plates and screws to hundreds of spine surgeons outside of the IDE trials exclusively for spine surgery and not for use in repairing long bone fractures. (Tr., p. 229). Among other things, AcroMed sponsored and conducted training sessions for hundreds of spine surgeons at which they were instructed in the use of AcroMed's plates and screws in the spine without disclosing that this was an experimental use not approved by the FDA outside of the IDE trials. (Tr., p. 332). AcroMed prepared and exhibited a film showing use of its plates and screws exclusively in spinal applications. (Tr., p. 229). It offered the device for sale through a catalog which described it as a "spinal fixa-

tion system." (Tr., pp. 238-239, 452-453; Pl. Ex. #30). AcroMed refused to supply the device for use by any physician unless and until that physician was trained in spinal application of the device. (Tr., pp. 290, 332). Finally, at trial, AcroMed failed to offer any evidence that the device was ever marketed or promoted for use in repairing fractures of the long bones.

In the Fall of 1985, Clark Gunderson, M.D., an orthopedic surgeon practicing in Lake Charles, Louisiana, attended a program in Cleveland, Ohio at which AcroMed's principal stockholder and director, Arthur Steffee, M.D., instructed spine surgeons concerning the use of AcroMed's plates and screws in treating spinal pathology. (Tr., pp. 289-290, 395). In February, 1986 plaintiff, Dorothy Marie Reeves, was admitted to Lake Charles Memorial Hospital where she came under the care of Dr. Gunderson for treatment of a bulging disc between her fourth and fifth lumbar vertebrae. Dr. Gunderson contemplated performing spinal fusion surgery on Mrs. Reeves using AcroMed's plates and screws. However, he was concerned that such a use would be unlawful. (Tr., pp. 412-414). Accordingly, he contacted AcroMed to determine the regulatory status of the device for spinal indications. (*Ibid.*) AcroMed told him that it was perfectly legal to use the device in the spine. (*Ibid.*) The company never disclosed to Dr. Gunderson that the FDA had twice refused to clear the device for use in the spine and that its use for this purpose was considered "experimental" by both AcroMed and the FDA. (Tr., p. 289). Based on AcroMed's assurances, Dr. Gunderson implanted AcroMed's VSP Spine Plate Fixation System in Mrs. Reeves' spine in the manner recommended by Dr. Steffee. (Tr., pp. 412-413).

Mrs. Reeves did reasonably well for the first eight months following surgery. (Tr. pp. 148 & 174). However, her condition began to deteriorate in September of 1986. (Tr. pp. 178, 175-176). X-rays revealed precisely what the FDA had been concerned with — two of the screws inserted in Mrs. Reeves' back had broken causing damage to the nerve roots innervating the right leg and a lack of fusion. (Tr. pp. 149). As a result, she experienced increasing levels of pain in her lower back and right leg; the lower spine exhibited instability; her ability to walk was impaired; and she exhibited muscle wasting in her

right calf. (Tr. at pp. 148-149; 152-153; 175-176 & 179). These conditions are extremely painful and debilitating.

C. Proceedings in the District Court and Court of Appeals

On December 27, 1991 plaintiff brought suit against AcroMed Corporation to recover damages for the injuries which she sustained as a result of the surgical use of the VSP Spine Plate Fixation System. The suit was brought in the United States District Court for the Eastern District of Louisiana. Jurisdiction was predicated on diversity of citizenship.

The case was tried before a jury from August 30, 1993 through September 1, 1993. At the conclusion of the evidence, the jury was asked to respond to four special verdict questions. The first of these questions asked "Was the AcroMed product implanted in Dorothy Reeves' spine unreasonably dangerous as a spinal implant?" (Tr., p. 572). With regard to this interrogatory, the jury was instructed that it could properly find that the product was unreasonably dangerous if it found that the product was unreasonably dangerous in construction, that the product was unreasonably dangerous in design, that the supplier of the product did not give the user adequate warning concerning the dangers of the product or if the product was "unreasonably dangerous per se" — that is, that "a reasonable person would conclude that the danger in fact, whether foreseeable or not, outweighs the utility of the product." (Tr., pp. 572-576).

The jury unanimously concluded that the AcroMed product implanted in Dorothy Reeves' spine was unreasonably dangerous as a spinal implant. (A-7). It also determined in response to specific questions that AcroMed did not "legally obtain FDA approval for the AcroMed product to be implanted in the spine except in an investigative or experimental program prior to the time that it was implanted in Dorothy Reeves" and that if Mrs. Reeves had been informed that the AcroMed product was experimental and under investigation she would not have permitted it to be implanted in her back. *(Ibid).* Finally, the jury determined that Mrs. Reeves was entitled to $475,000.00 to "adequately compensate for her damages caused by the implantation in her spine of the AcroMed product." *(Ibid).* A

remittitur was entered and the post trial motions were otherwise denied. Plaintiff accepted the remittitur and judgment was entered against AcroMed and its insurer, St. Paul Fire & Marine Insurance Company, on October 14, 1993 in the amount of $410,000.00.

On October 27, 1993 AcroMed and St. Paul appealed to the United States Court of Appeals for the Fifth Circuit. The decision of the Court of Appeals was announced on February 10, 1995. In its Opinion, the Appellate Court determined that the Medical Device Amendments to the FDA preempted plaintiff's failure to warn claim — that is, the claim that AcroMed's plates and screws were unreasonably dangerous because AcroMed failed to adequately warn her and her physician of the product's dangers, including its experimental nature and its regulatory status. (A-17). Because of this, the Court vacated the judgment. Plaintiff timely filed a Petition for Rehearing which was denied by the Court of Appeals on April 3, 1995.

REASONS FOR GRANTING THE WRIT

As we will demonstrate, the exercise of this Court's review powers is essential because the Fifth Circuit's decision is directly at odds with the preemption decisions of its sister circuits and forms part of a pattern of rapidly escalating conflict among this nation's appellate courts concerning the extent to which tort claims involving medical devices are preempted by federal law. Absent action by this Court to establish a uniform rule for preemption in the medical device field, this increasing conflict threatens to consume a large quantum of judicial resources and to undermine the socio-legal values of predictability and consistency for that huge segment of commerce involving health care.

* * *

Section 521(a) of The Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 *U.S.C.* §360k(a), sets forth an express provision for preemption of state laws. It states:

> "[N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement — (1) which

> is different from, or in addition to any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

21 *U.S.C.* §360k(a).

This statutory language is plainly subject to varying interpretations. Given other provisions of the statute[5], its legislative history[6], and the applicable presumptions against preemption[7],

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5. In other sections of the statute, Congress explicitly manifested an intent that common law liability would remain in conjunction with FDA regulation. Specifically, 21 *U.S.C.* §360h(d) defines the effect of a manufacturer's compliance with an FDA notification, reimbursement, or recall order as follows:

> "Compliance with an order issued under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account."

6. The MDA was enacted in order to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." *S.Rep.No.* 33, 94th Cong. 2d Sess. 5, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1075. As stated by the sponsor of the legislation when introducing the bill on the Senate floor, "the legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 *Cong.Rec.S.* 6140 (April 17, 1975).

7. There is a "presumption that state or local regulation of matters related to health and safety is not invalidated under" preemption principles. *Hillsborough County v. Automated Medical Lab*, 471 U.S. 707, 715 (1985). Given this "strong presumption," preemption enactments are to be read "fairly but narrowly" in relation to state laws governing health and safety. *E.g., Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2621 (1992). Moreover, there is an even stronger presumption that Congress would not, in the exercise of its plenary powers, "remove all means of judicial recourse for persons injured" by preempting traditional damage remedies available to injured persons under state law without providing a substitute damage remedy under federal law. *Silkwood v. Kerr McGee Corp.*, 464 U.S. 238, 250-51 (1984); *United Construction Workers v. Laburum Construction Corp.*, 347 U.S. 656, 663-64 (1954).

the statute is entitled to a narrow construction which preserves the exercise of the state's historic powers over matters of health and safety to the extent reasonably consistent with the statutory language. A fair but narrow reading of the statute is that state law will not be preempted unless there is both a state requirement and a federal requirement which have the same subject matter and which **both** apply to a **specific** device as distinguished from laws of general application to all devices or to products in general.

This is precisely the construction adopted by the FDA in regulations which it promulgated in 1978. These regulations, intended to implement the provisions of Section 521(a), 21 *U.S.C.* §360k(a), specifically provide:

> "State or local requirements are preempted only when the Food and Drug Administration has established ***specific counterpart regulations*** or there are other ***specific requirements*** applicable to a ***particular*** device under the Act, thereby making any existing divergent state or local requirements applicable to **the device** different from, or in addition to, the specific Food and Drug Administration requirements. There are other state or local requirements that affect devices that are not preempted by Section 521(a) of the Act because they are not 'requirements applicable to a device' within the meaning of Section 521(a) of the Act. The following are examples of state or local requirements that are not regarded as preempted by Section 521 of the Act:
>
> (1) ***Section 521(a) does not preempt state or local requirements of general applicability where the purpose or the requirement relates either to other products in addition to devices*** (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices;

(2) Section 521(a) does not preempt state or local requirements that are equal to or substantially identical to requirements imposed by or under the Act."

21 C.F.R. §808(d)(1) & (2)(emphasis supplied).

For the first thirteen years following enactment of the MDA, few defendants claimed that state laws were preempted by the MDA and the Court decisions followed the preemption formula established by the FDA regulation.[8]

This decade has, however, seen an exponential increase in the assertion of federal preemption as a defense to damage claims under state law for injuries caused by allegedly defective medical devices.[9] In response to the increasing press of this defense, courts have abandoned that side of the FDA's equilateral preemption equation which requires a state "requirement" relating to a ***specific*** device as a condition to preemption. Indeed, despite the repeated admonition of this Court that regulations such as the FDA's preemption regulation are entitled to substantial deference[10] and despite the fact that the FDA's preemption regulation plainly provides that state laws of general applicability, like most state tort laws, are not preempted by the MDA, the recent decisions are virtually unanimous in holding otherwise.[11] However, the Courts have generally adhered to the other half of the FDA's preemption syllogism, holding that even state laws of general applicability

8. During the period from 1976-1989 there were seven federal district court decisions, three state decisions, and no federal appellate decisions which were reported in the West System dealing with the subject of preemption under the MDA. In contrast, during the period beginning 1992, there have been fourteen decisions by federal courts of appeal, fifty federal district court decisions and ten state court decisions reported on the subject in the West Reporting System.

9. *See* footnote 8, *supra*.

10. *See: Chevron United States, Inc. v. National Resource Defense Counsel, Inc.*, 467 U.S. 837 (1984); *Bowels v. Seminole Rock & Sand Co.*, 325 U.S. 410, 415 (1945).

11. *See, e.g., Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir. 1994); *Mendes v. Metronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Stamps v. Collegen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. den.*, 114 S.Ct. 86 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. den.*, 113 S.Ct. 327 (1992).

will only be preempted where there is a "specific FDA requirement applicable to a particular device" and then only to the extent fairly encompassed within the subject matter of the FDA's device specific regulation.[12]

To be sure, the application of this rule in the context of the MDA's highly convoluted regulatory scheme has resulted in increasingly conflicting decisions by federal and state courts at both the trial and appellate levels.[13] However, until the Fifth Circuit's decision in this case four bedrock principles, derived from the general rule espoused by the Courts, were uniformly applied and served to provide a somewhat steady compass by which to navigate the resolution of the question of whether the MDA preempted a particular tort claim in any given case.

The first of these bedrock principles is that state law claims arising from conduct which violates federal medical device law are not preempted because the imposition of liability on a defendant for conduct which violates federal law cannot be considered as imposing substantive duties which are "inconsistent with or in addition to" the duties which a defendant has under the Food, Drug and Cosmetic Act. This rule is plainly expressed in the FDA's preemption regulations:

> "Section 521(a) [21 *U.S.C.* §360k] does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act."

21 *C.F.R.* §808.1(d)(2).

The Rule has also been articulated in decisions by the United States Courts of Appeal for Eighth and Third Circuits. In *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994), the Eight Circuit squarely ruled in relation to the preemption provisions of the MDA that:

"We agree with the conclusions of the *Worm*[14] and

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12. *See* footnote 11, *supra.*

13. *See* pages 26-28, *infra.*

14. *Worm v. American Cyanamid Co.*, 970 F.2d 1301 (4th Cir. 1992).

> *Moss*[15] Courts and of the District Court cited above that when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements."

Id. at 993.

This Rule was emphasized by the Third Circuit in its recent decision in *Michael v. Shiley*, 46 F.3d 1316 (3rd Cir. 1995). There, the Court found that an express warranty claim which was predicated on the violation of an FDA approved warranty survived MDA preemption because:

> "[T]he enforcement of an express warranty that arises from approved packaging does not establish a requirement that 'is different from or in addition to, . . . any requirement applicable under this chapter to the device.' 21 *U.S.C.* §360k. Through her express warranty claim Michael seeks to enforce the very language which the FDA approved on the Shiley valve label . . . Thus, it is the FDA's own requirement that Michael would have the state enforce. If any person other than Shiley 'established' the warranty, it was the FDA, not the state. Because the obligations imposed arise directly from the FDA's own approved language, the resulting liability does not differ or add to FDA regulation. Rather, it supports the FDA's approval regulation by giving it effect."

Id. at 1327-28. Other cases are in accord.[16]

Second, the FDA regulations and decisions by the Hawaii

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15. *Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir.), *cert. den.*, 113 S.Ct. 2919 (1993).

16. *See Slater*, 961 F.2d at 334 (preemption under MDA is 'limited to efforts by states to impose sanctions for compliance with federal regulations'); *Reiter v. Zimmer*, 830 F.Supp. 199, 204 (S.D.N.Y. 1993) (refusing to extend preemptive reach of MDA to a negligence claim against a manufacturer that allegedly violated FDA requirements); *Minister of Health v. Shiley*,

Supreme Court and the Circuit Courts of Appeal have explicitly recognized that an FDA decision to clear a device for market pursuant to a 501K premarket notification normally represents a determination by the agency that the device is substantially equivalent to a predicate device and does not amount to "approval" of the product or otherwise represent a substantive determination that it is safe, effective, or properly labeled. *See* 21 *C.F.R.* §807.97 (a finding of substantial equivalence "does not in any way denote official approval of the device"); *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 650, 837 P.2d 1273, 1282, *amended on partial grant of reconsideration*, 74 Haw. 650, 843 P.2d 144, (1992) ("although a determination of substantial equivalence involves a review by FDA of what is known of the safety and effectiveness of the device, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness"); *National Bank of Commerce v. Kimberly Clark Corp.*, 38 F.3d 988, 998 (8th Cir. 1994) ("an FDA Order permitting [a] new device to be marketed as substantially equivalent to existing devices would not normally reflect agency approval of the submitted labels"); *Stamps v. Collogen Corp.*, 984 F.2d 1416, 1423, n. 6 (5th Cir.), *cert. den.*, 114 S.Ct. 86 (1993) ("FDA does *not* officially approve 'substantially equivalent' devices"). *See also*, fn. 3, *supra*. Therefore, imposition of liability under state law on the basis that a device is unsafe or improperly labeled is not "inconsistent with" a decision to clear the device for market pursuant to a Section 510k premarket notification and, therefore, not preempted. *See Lamontagne v. E.I. Dupont de*

Footnote 16—Continued

Inc., 858 F.Supp. 1426, 1439 (N.D. Cal. 1994) ("the MDA would not preempt claims if the manufacturer negligently failed to comply with the FDA's regulations since a finding of wrongdoing would merely impose those regulations already imposed by the statute and it would not be 'different from or in addition to' those imposed by the MDA"). *Evraets v. Intermedics Interocular, Inc.*, 29 Cal.App. 4th 779, 34 Cal.Rptr.2d 852 (1994) ("state actions which echo or attempt to enforce federal standards are not preempted"). *Cf.*, *Mendes v. Medtronic*, 18 F.2d 13, 19-20 (1st Cir. 1994) ("we express no opinion on whether product liability claims are preempted only if a manufacturer complied with applicable FDA regulations").

Nemours & Co., 41 F.3d 846, 853-854 & 855 (2d Cir. 1994); *Larsen*, 837 P.2d at 1282; *OJA v. Howmedica, Inc.*, 848 F.Supp. 905 (D. Col. 1994); *Fogal v. Steinfeld*, 620 N.Y.S. 2d 875, 882-883 (1994).

The third bedrock principle of preemption analysis as to which there has been uniform judicial consensus was announced in decisions by the Second and Ninth Circuit Courts of Appeal in *Anguiano v. E.I. DuPont DeNemours & Co., Inc.*, 44 F.3d 806, 809-811 (9th Cir. 1995) and *Lamontagne v. E.I. Dupont de Nemours & Co., Inc.*, 41 F.3d 846, 853-855 (2d Cir. 1994) as well as in numerous District Court decisions.[17] This principle holds that in the absence of "special controls," damage claims under state law which arise from the use of a Class I or Class II medical device are not preempted because the degree of regulation applicable to such devices does not rise to the level of a federal "requirement" for preemption purposes. *Id.*

Finally, the MDA preemption jurisprudence has consistently held that neither the general regulation of devices by the MDA nor the failure by the FDA to exercise its powers of regulation with respect to a given device can form a basis for preemption of state law damage claims. *E.g.*, *National Bank of Commerce*, 38 F.3d 988 at 997; *Lamontagne*, 41 F.3d at 853-854 & 855; *Mulligan v. Pfizer, Inc.*, 859 F.Supp. 633 (S.D.Ohio 1994); *Ginochio*, 864 F.Supp. at 956; *OJA v. Howmedica, Inc.*, 848 F.Supp. 905, 907 (D. Col. 1994). This principle is evinced in the recent decision by the Eighth Circuit Court of Appeals in *National Bank of Commerce*, a product liability case relating to tampons. There, the Court declined to find that plaintiffs' state law claims regarding the testing, design and manufacture of a tampon product were preempted by the MDA based on the fact that tampons were generally subject to regulation as Class II devices and on the fact that the FDA chose not to specifically regulate the testing, design and manufacture of tampons:

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17. *See, e.g., Ginochio v. Surgikios, Inc.*, 864 F.Supp. 948, 952-54 (N.D.Cal. 1994).; *Oliver v. Johnson and Johnson, Inc.*, 863 F.Supp. 251, 254-55 (W.D. Pa. 1994); *Parenteau v. Johnson & Johnson, Inc.*, 856 F.Supp. 61, 63-64 (D.N.H. 1994); *Brown v. Medtronic*, 852 F.Supp. 717, 721 (S.D.Ind. 1994);

> "Finally, Kimberly Clark suggests that the FDA considered broader regulation of tampons and chose to limit its regulation to labeling. As a result, it says we should treat the FDA's considered decision not to regulate broadly as preempting National Bank's claims involving testing, design and manufacture. Such a holding is precluded by the FDA's own regulations, but in addition, it would evince total disregard for the structure of our federal system. Absent clear statutory language to the contrary (or ambiguous statutory language accompanied by reasonable agency interpretation to the contrary), it would be anomalous to suggest that the FDA may preempt all possible tort actions involving a particular product simply by placing it into a class or by imposing some general control. To the extent that Kimberly Clark's argument rests solely on Section 360k(a), it applies equally to medical devices placed into any one of the three categories. Thus, were we to accept Kimberly Clark's argument, the FDA would preempt any and all tort actions against manufacturers of say, crutches or tongue depressors, simply by placing those items in Class I. We reject this argument as inconsistent with both our and the FDA's reading of the MDA's preemption provision."

Id., 38 F.3d at 997.

This Court's recent ruling in *Freightliner Corp. v. Myrick*, 1995 W.L. 224617 (U.S., April 18, 1995), underscores and reinforces the conclusion that an agency's failure to exercise its regulatory power does not constitute implicit regulation capable of preempting state law. In *Freightliner*, the Court explicitly rejected the argument that "the failure of federal officials affirmatively to exercise their full authority takes on the character of a ruling that no such regulation is appropriate" for purposes of express preemption analysis. *Id.* at *3.

* * *

The Fifth Circuit's decision in the present case is directly at odds with these four principles of preemption analysis. In

finding plaintiff's "failure to warn" damage claim preempted, the Fifth Circuit began its analysis by correctly noting that the device at issue was cleared for market pursuant to a Section 510k premarket notification on the basis that it was substantially equivalent to Class II devices in commerce prior to May 28, 1976 for use in repairing long bone fractures. *See Reeves*, 44 F.3d at 303-04. The Opinion characterized this clearance decision as an "approval" of the device "for marketing". *Id.* 303-04. It then opined that "FDA regulations require device manufacturers to submit the proposed labeling and warnings for their devices to the FDA as part of the approval process" leading to such approval, that "FDA labeling regulations specifically require labels to disclose a device's uses, hazards, side effects, and any applicable precautions," that "the regulations also require the FDA to review AcroMed's labeling to ensure that it was in compliance with [these] general labeling regulations" as part of the "approval process," and that "based on its review of the manufacturer's proposed labeling, the agency can impose additional labeling requirements if it determines that 'a substantial deception' or unreasonable health danger could be corrected by 'labeling or change in labeling.'" *Id.* at 304-05. Given this view of the applicable regulatory context, the Opinion concluded that:

> "The FDA thus implicitly approves the manufacturer's proposed labeling when the agency approves the device for marketing. Because Reeve's failure to warn claim would impose labeling requirements beyond those required by the FDA, her claim runs afoul of §360k(a) of the MDAs.

Id. at 304. The Court further concluded that plaintiff's failure to warn claim was not saved from the preemptive reach of Section 360k(a) by virtue of the fact that it was predicated on conduct which was in violation of the mandates of federal medical device law.[18] In this regard, the Court reasoned:

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18. Plaintiffs' failure to warn claim under state law was squarely predicated on conduct by AcroMed in violation of the Medical Device Amendments and their implementing regulations in at least four different ways.

Footnote 18—Continued

First, in response to two premarket notifications filed by AcroMed, the FDA determined that AcroMed's VSP system of bone plates and bone screws was a Class III medical device when intended for use in spinal fixation procedures. Under federal law, it is illegal to sell a Class III device without obtaining premarket approval from the agency to do so. *See* 21 *U.S.C.* §§360c(a)(1)(C) & 360e; *Simon v. Ravenswood Hospital Medical Center*, 814 F.Supp. 33 (N.D. Ill. 1992); *United States v. An Article of Device*, 687 F.Supp. 990 (W.D. Mich. 1985). Indisputably, AcroMed never received premarket approval to sell its plates and screws. Therefore, AcroMed would plainly violate federal law if it sold its plate and screw system with the intent that it be used exclusively in spinal fixation procedures. Here, plaintiff established to the satisfaction of the jury that that is exactly what happened.

Second, when AcroMed changed the name of the device which the FDA refused to approve as a "spinal fixation system" and filed the third and fourth premarket notifications by which it ultimately obtained FDA clearance to market its plate and screws device (representing that the device components were substantially equivalent to bone plates and bone screws employed in the repair of long bone fractures) it was required to provide the agency with "proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for its use." *See* 21 *C.F.R.* §807.87(e). Indisputably, none of the proposed labeling for AcroMed's "bone plates" and "bone screws" which was contained in the third and fourth premarket notifications revealed spinal fixation as an "intended use" of the device. However, in the present case plaintiff established to the satisfaction of the jury that this was, in fact, the sole intended use of the device. Consequently, Acromed indisputably violated the provisions of Section 807.87(e) of the FDA's regulations.

Third, when used in the spine, AcroMed's plate and screw device was an investigational device. FDA regulations plainly prohibited commercial distribution of such a device. *See* 21 *C.F.R.* §812.7(a). Here, plaintiff established to the satisfaction of the jury that defendant commercially distributed its VSP device in violation of this regulation.

Finally, the FDA's prescription device labeling regulation requires that all prescription medical devices have labeling which contains all relevant information "under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented." See 21 *C.F.R.* §801.109(c) & (d). In this case, it is undisputed that the labeling which accompanied AcroMed's "bone plates" and "bone screws" did not contain any information concerning any spinal applications of the device or its components. However, the jury plainly concluded that this was the sole purpose for which the plates and screws were intended and marketed. Therefore, AcroMed clearly violated Section 801.109 of the regulations by failing to label its device for its intended use.

> "Allowing a jury or court to second guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in Section 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."

Id. at 307 (citations omitted).

Plainly, the Fifth Circuit's decision misapprehends the nature and content the relevant regulations.[19] In addition, the Circuit Court's decision undermines the Congressional purpose underlying the 510k pathway to market.[20] For purposes of this Petition, however, the most important aspect of the Fifth Circuit's ruling is that it directly conflicts with recent decisions by other Appellate courts in both the State and Federal systems.

In expressly "declin[ing] to create an exception to preemption under the MDAs in cases where manufacturers allegedly violated FDA . . . regulations", the Fifth Circuit's decision is directly in conflict with the Third Circuit's Ruling in *Michael*, the Eighth Circuit's decision in *National Bank of Commerce* and California Court of Appeals Opinion in *Evraets*. *See* pps. 18-19, *supra*.

In holding that an FDA clearance to market pursuant to a Section 510k premarket notification constitutes a regulatory "approval" which serves as a basis for preemption of state law remedies, the Fifth Circuit's decision here is directly contrary to the decision of the Hawaii Supreme Court in *Larsen* and the

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19. *See* pp. 5-6, & *fn.* 3 *supra*.

20. By holding that preemption arises from an FDA substantial equivalence response to a 510K premarket notification, the Fifth Circuit has effectively ruled that new products which are required to obtain 510k clearance will be immune from tort liability under state law while the predicate devices to which they are substantially equivalent will not enjoy such tort immunity because they do not require similar regulatory clearance. This directly contradicts Congress' expressed intent that there be no competitive disparity between substantially equivalent pre-enactment and post-enactment devices. Adler, R. and Mann, R. "Preemption and Medical Devices: The Courts Run Amok," 59 *Missouri L.Review* 895, 914 (1994).

First Circuit's finding in *Mendes*. Arguably, it is also at odds with the Fifth Circuit's prior decision in *Stamps*. *See* pps. 19-21, *supra*.

In holding that preemption applies to claims arising from a device which did not receive premarket or IDE approval, which was not subject to any FDA "special controls," and which was cleared for market as a Class II device, the Fifth Circuit's decision is in direct conflict with the holding of the Second Circuit in *Lamontagne* and the decision of the Ninth Circuit in *Anguiano*. *See* p. 21, *supra*.

Finally, to the extent that the Fifth Circuit's decision finds preemption based on an "implicit" FDA determination which is thought to arise from the agency's failure to exercise its powers of regulation with respect to a device, such as its failure to prescribe labeling or a change in labeling with respect to AcroMed's plate and screw device, the decision is in direct conflict with this Court's decision in *Freightliner* and the Eighth Circuit's express ruling in *National Bank of Commerce*. *See* pp. 21-22, *supra*.

The multiple conflicts which plainly exist between the Fifth Circuit's decision and other appellate authorities do not represent an idiosyncratic quirk in the judicial process. Rather, they form part of a larger pattern of conflict which has been increasingly animated by two fundamental problems. First, the MDA's preemption provision is patently ambiguous. This necessarily engenders conflicting judicial interpretation of its terms. Second, unlike preemption under the Public Health Cigarette Smoking Act of 1969 which was at issue in *Cipollone*, preemption under the National Traffic and Motor Vehicle Safety Act of 1966, 15 *U.S.C.* §1381 et seq., which was at issue in *Freightliner*, or similar provisions like the Federal Insecticide Fungicide and Rodenticide Act, 7 *U.S.C.* §136v, and the Federal Hazardous Substances Act, 15 *U.S.C.* §1261, preemption under the Medical Device Amendments has judicially been made to be dependent on the precise regulatory status of varying products under a highly reticular regulatory scheme. Because of the complexity of that scheme and the courts' understandable lack of familiarity with it, mistakes and inconsistencies in regulatory interpre-

tation are inevitable as are the inconsistencies in preemption analysis which necessarily flow from such errors.

These two factors, as well as others, have combined to produce significant conflicts in addition to those presented by the Fifth Circuit's decision in the instant case. For example, the First Circuit's decision in *King* holds that state law claims of fraud on the market and breach of express warranty are preempted with respect to devices which have received premarket approval while the Third Circuit's decision in *Michael* holds that express warranty and fraud on the market claims are not preempted, even with regard to devices which have received premarket approval from the FDA. *Compare, e.g., King vs. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993), *with Michael*, 46 F.3d at 1326-27 & 1329-30 (3d Cir. 1995). By way of further example, *Michael* expressly holds that claims of fraud on the FDA are preempted while a recent decision by the California Court of Appeals rejects this approach and holds that such claims are not preempted. *Compare, Michael*, 46 F.3d at 1328-29 *with Evraets*, 29 Cal.App. 4th 779, 34 Cal.Rptr. 2d 852. Further, the First Circuit's decision in *Mendes* holds that preemption may be based on general regulatory controls while the decisions of the Second Circuit in *Lamontagne* and the Ninth Circuit in *Anguiano* expressly rule that "general controls" are not a sufficient regulatory predicate for preemption. *Compare, Mendes*, 18 F.3d at 18-19 *with Anguino*, 44 F.3d at 809-10 and *Lamontagne*, 41 F.3d at 853-55. In addition, language used by the Ninth Circuit in *Anguiano* implies that tort claims with respect to any device cleared for market as a Class III device are preempted while other decisions appear to hold that premarket approval is a prerequisite to across the board preemption of tort claims for Class III devices. *Compare, Anguino*, 44 F.3d at 809-10 *with King*, 983 F.2d at 1135-36. Finally, several intermediate appellate decisions in the State systems as well as some Federal District Court decisions have held that the MDA does not preempt any state law tort claims while the bulk of the federal jurisprudence is obviously to the contrary. *Compare, e.g., Haudrich v. Howmedica, Inc.*, 267 Ill.App. 3d 630, 642

N.E.2d 206, 204 Ill. Dec. 744 (Ill.App. 5 Dist. 1994) and *Mulligan*, 850 F.Supp. at 635 *with Gile*, 22 F.3d 542-44 and *Mendes*, 18 F.3d at 17-20.

As is readily apparent, the current state of the law is such that there is respectable authority to support virtually any position which a litigant may wish to take with respect to the question of whether a particular claim under state law is preempted by the MDA for any particular medical device.

This situation of apparent legal confusion does not exist in some arcane area of human endeavor. As Congress found when it enacted and amended the MDA, medical devices are produced in large and ever increasing numbers.[21] While such devices hold the promise of great good, experience has proven that they pose a significant potential for causing devastating physical harm to large numbers of people.[22] Therefore, we are presented with a situation in which there are ongoing risks of harm to large numbers of people who are exposed to increasingly complex and numerous medical devices on a daily basis. At the same time, the pale of potential legal liability arising from such use cannot be ascertained because there is a pervasive uncertainty concerning the extent to which damage claims arising from the use of medical devices may properly be asserted under the preemption provisions of the MDA. This results in many adverse socio-legal consequences.

First, by reason of the pervasive uncertainty concerning preemption of medical device claims, device manufacturers and their insurers are not in a position to ascertain the nature and extent of the business risk which accompanies the marketing of a given medical device. The necessary effect of this is to

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21. *See* S.Rep.No. 33, 94th 2d Sess. reprinted in 1976, *U.S.C.C.A.N.* 1070, 1075 ("increasing number of patients have been exposed to increasingly complex devices which pose serious risk").

22. Among the key reports that convinced Congress to enact medical device legislation was one by a blue-ribbon committee of the Department of Health Education and Welfare called the Cooper Committee. *See* Study Group on Medical Devices, Department of Health, Education and Welfare, Medical Devices: A Legislative Plan (1970). According to the Copper Committee medical devices were involved in 10,000 injuries and 751 deaths during the previous ten years.

hamper meaningful business planning and risk underwriting. This in turn necessarily impedes the development of new and potentially beneficial devices as well as enhancing the danger that there will be inadequate resources to compensate the victims of ill conceived device technology.

Second, because the extent of MDA preemption is completely unsettled, a party who has suffered significant harm as a result of using a defective medical device cannot determine with any degree of assurance whether the damage claim which he or she might otherwise have under state law is viable. Therefore, unless and until the law in this area is settled, such parties will continue to bring claims seeking compensation for the harm which they have suffered, device manufacturers will always raise preemption as a defense to such claims, and the legal question of federal preemption will continue to be fully litigated through the appellate level in every one of these cases. Considering the large number of potentially harmful medical devices in commerce, this will produce an increasingly large consumption of resources by the courts and the litigants which could be better applied to the resolution of these cases on the merits, the compensation of injured victims and the development of improved device technology.

Finally, the growing inconsistency among the courts in resolving preemption questions will inevitably lead to forum shopping and will also produce a situation in which identical claims are treated differently with some users of a medical device being permitted to pursue their damage claims and other similarly situated users of the same medical device being summarily dismissed from court. Such a situation is inimical to basic notions of justice and necessarily serves to undermine public confidence in the rule of law.

By exercising its certiorari powers in the present case to determine and announce a uniform rule of preemption for medical device claims, this Court would eliminate growing confusion in a frequently litigated area and the concomitant social costs which that confusion continues to extract. Therefore, we submit, this is a quintessential case for the exercise of the Court's review powers.

CONCLUSION

For the foregoing reasons, Petitioner respectfully submits that the Court should grant her Petition for a Writ of Certiorari and review the Judgment and Opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 93-3752

DOROTHY MARIE REEVES,
Plaintiff-Appellee,

v.

ACROMED CORPORATION, et al.,
Defendants,

Acromed Corporation, et al.,
Defendants-Appellants.

OPINION OF THE COURT OF APPEALS
DATED FEBRUARY 10, 1995

Patient brought products liability action against manufacturer of metal bone implant that allegedly exacerbated injuries in plaintiff's back, alleging that defendant failed to warn her that Food and Drug Administration (FDA) never approved implant for use in spine except as part of controlled investigational study. Plaintiff also asserted defective manufacturing, defective design, and unreasonably dangerous per se claims. The United States District Court for the Eastern District of Louisiana, Adrian G. Duplantier, J., entered judgment on jury verdict for plaintiff. Defendant appealed. The Court of Appeals, W. Eugene Davis, Circuit Judge, held that: (1) medical device amendments (MDA) preempted failure to warn claims, and (2) jury question was presented as to whether implant was unreasonably dangerous per se under Louisiana law.

Vacated and remanded.

[1] FEDERAL COURTS k937.1
170Bk937.1

When district court submits two or more alternative grounds for recovery to jury on single interrogatory and plaintiff prevails, Court of Appeals ordinarily orders new trial if one ground for recovery is legally inadequate.

[2] FEDERAL COURTS k907
170Bk907

If trial court erroneously submitted one legal theory of recovery to jury and form of interrogatory prevents Court of Appeals from determining upon which theory jury based its verdict, Court of Appeals must vacate judgment.

[3] PRODUCTS LIABILITY k46
313Ak46

Medical device amendments (MDA) preempted claim that defendant metal bone implant manufacturer failed to adequately warn plaintiff and her physician that Food and Drug Administration (FDA) never approved implant for use in spine except as part of controlled investigational study; labeling for impact was approved through FDA's premarket notification process, and patient's failure-to-warn claim would impose labeling requirements beyond those required by FDA. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a); 21 C.F.R. § 808.1(d)(6).

[3] STATES k18.65
360k18.65

Medical device amendments (MDA) preempted claim that defendant metal bone implant manufacturer failed to adequately warn plaintiff and her physician that Food and Drug Administration (FDA) never approved implant for use in spine except as part of controlled investigational study; labeling for implant was approved through FDA's premarket notification process, and patient's failure-to-warn claim would impose labeling requirements beyond those required by FDA. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a); 21 C.F.R. § 808.1(d)(6).

[4] PRODUCTS LIABILITY k46
313Ak46

Preemptive effect of Food and Drug Administration (FDA) labeling regulations under medical device amendments (MDA) applies equally to devices approved under FDA's premarket approval procedures (under which applicant must demonstrate that its device is "substantially equivalent" to device on market prior to MDAs' effective date), and devices approved under premarket notification procedures (under which FDA approves application only after extensive review by agency and advisory committee composed of outside experts). Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.D.A. § 360k(a); 21 C.F.R. §§ 807.87, 814.20.

[4] STATES k18.65
360k18.65

Preemptive effect of Food and Drug Administration (FDA) labeling regulations under medical device amendments (MDA) applies equally to devices approved under FDA's premarket approval procedures (under which applicant must demonstrate that its device is "substantially equivalent" to device on market prior to MDAs' effective date), and devices approved under premarket notification procedures (under which FDA approves application only after extensive review by agency and advisory committee composed of outside experts). Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.D.A. § 360k(a); 21 C.F.R. §§ 807.87, 814.20.

[5] PRODUCTS LIABILITY k46
313Ak46

Medical device amendments (MDA) preempted failure to warn claim against manufacture of metal bone implant, even though implant was used in spine—"off-label" use—rather than in long bones of upper or lower extremities, as stated in manufacturer's application to Food and Drug Administration (FDA); FDA labeling regulations specifically address off-label uses of medical devices. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A § 360k(a); 21 C.F.R. §§ 801.4, 895.25.

[5] STATES k18.65
360k18.65

Medical device amendments (MDA) preempted failure to warn claim against manufacture of metal bone implant, even though implant was used in spine—"off-label" use—rather than in long bones of upper or lower extremities, as stated in manufacturer's application to Food and Drug Administration (FDA); FDA labeling regulations specifically address off-label uses of medical devices. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A § 360k(a); 21 C.F.R. §§ 801.4, 895.25.

[6] PRODUCTS LIABILITY k46
313Ak46

Medical device amendments (MDA) preempted failure to warn claim against manufacturer of metal bone implant, despite claim that manufacturer misled Food and Drug Administration (FDA) and violated FDA regulations by withholding material information from FDA concerning intended uses of its product; given FDA's central role in reviewing and approving devices under MDA, FDA was in best position to decide whether manufacturer withheld material information from agency and, if so, appropriate sanction. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a).

[6] STATES k18.65
360k18.65

Medical device amendments (MDA) preempted failure to warn claim against manufacturer of metal bone implant, despite claim that manufacturer misled Food and Drug Administration (FDA) and violated FDA regulations by withholding material information from FDA concerning intended uses of its product; given FDA's central role in reviewing and approving devices under MDA, FDA was in best position to decide whether manufacturer withheld material information from agency and, if so, appropriate sanction. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a).

[7] PRODUCTS LIABILITY k11
313Ak11

To prevail on defective design theory under Louisiana law, plaintiff must establish existence of alternative safer design for product.

[8] PRODUCTS LIABILITY k88
313Ak88

Jury question was presented under Louisiana law as to whether metal bone implant manufactured by defendant and used to secure patient's vertebra while bone fused was unreasonably dangerous per se; in rejecting defendant's original application to have its implant approved as spinal implant, Food and Drug Administration (FDA) expressed concern about stability of device in that screws could break and damage bones in spine, and evidence would allow jury to infer that screws broke and exacerbated patient's back pain.

[9] PRODUCTS LIABILITY k26
313Ak26

While "unreasonably dangerous per se" theory under Louisiana law eliminated "state of the art" defense, plaintiff is not relieved of burden of proving that product is defective.

[9] PRODUCTS LIABILITY k75.1
313Ak75.1

While "unreasonably dangerous per se" theory under Louisiana law eliminated "state of the art" defense, plaintiff is not relieved of burden of proving that product is defective.

[10] PRODUCTS LIABILITY k8
313Ak8

To support recovery under theory that product is unreasonably dangerous per se under Louisiana law, plaintiff must establish that some inherent characteristic of product renders it unreasonably dangerous.

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Darryl J. Tschirn, La Jolla, CA, John J. Cummings, III, Frank C. Dudenhefer, Jr., Cummings, Cummings & Dudenhefer, New Orleans, LA, for appellee.

Appeal from the United States District Court for the Eastern District of Louisiana.

Before JOHNSON, HIGGINBOTHAM and DAVIS, Circuit Judges.

W. EUGENE DAVIS, Circuit Judge:

This appeal arises from a products liability action filed by the appellee, Dorothy Marie Reeves ("Reeves"), alleging that a metal bone implant manufactured and marketed by the appellant, AcroMed Corporation ("AcroMed") exacerbated injuries in her back. The central issue presented on appeal is whether the Medical Device Amendments *302 (the "MDAs") to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "Act"), preempt Reeves' claim that AcroMed failed to adequately warn her and her physician of the implant's dangers. AcroMed also challenges the evidentiary sufficiency of Reeves' defective manufacturing, defective design, and unreasonably dangerous per se claims. For the reasons stated below, we conclude that Reeves' failure-to-warn claim is preempted and that Reeves failed to produce sufficient evidence to recover on her defective manufacturing and defective design theories. We thus vacate the district court's judgment and remand this case for retrial of Reeves' action predicated on her unreasonably dangerous per se theory of recovery.

I.

In December 1985, Dorothy Marie Reeves seriously injured her back. In an effort to correct Reeves' condition, her neurosurgeon attempted a complicated surgical procedure designed to fuse the vertebrae at the four levels of the spine affected by the injury. As part of this surgery, Reeves' neurosurgeon implanted metal bone plates and screws manufactured by AcroMed to secure Reeves' vertebrae while the bone

fused. Reeves' condition initially improved after the surgery. X-rays taken of Reeves' back throughout the two years following surgery revealed no complications. Six months after the surgery, however, Reeves complained of increasing pain in her back that had not existed before the surgery. In December 1991, Reeves filed the present suit contending that AcroMed's metal bone implant broke and prevented the bones in her spine from fusing. She based her claim on a number of theories, including negligence, strict liability, breach of warranty, and battery. However, Reeves' primary theory at trial was that AcroMed failed to warn her that the Food and Drug Administration (the "FDA") never approved AcroMed's implant for use in the spine except as part of a controlled investigational study.

At the close of trial, the district court submitted three special interrogatories on liability to the jury. The jury found AcroMed's device unreasonably dangerous as a spinal implant and that AcroMed did not legally obtain FDA approval to market its device as a spinal implant. The jury also found that Reeves would not have permitted her surgeon to implant AcroMed's device if she had known that the device was unapproved for use in the spine.[1] The jury assessed Reeves' damages at $475,000, and the district court entered judgment on the verdict against AcroMed for that amount.

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1. The jury answered the interrogatories as follows:

INTERROGATORY NO. ONE:

Was the AcroMed product implanted in Dorothy Reeves' spine unreasonably dangerous as a spinal implant?

YES X NO

INTERROGATORY NO. TWO:

Did AcroMed legally obtain FDA approval for the AcroMed product to be implanted in the spine except in an investigative or experimental program, prior to the time it was implanted in Dorothy Reeves?

YES NO X

INTERROGATORY NO. THREE:

If Dorothy Reeves had been informed that the AcroMed product was experimental and under investigation would she have permitted it to be implanted in her back?

YES NO X

The district court instructed the jury that they could find AcroMed's product unreasonably dangerous and answer Interrogatory One "Yes" based on any of Reeves' four theories of recovery: defective design, defective manufacturing, failure-to-warn, and the "unreasonably dangerous per se" doctrine. AcroMed contends that the evidence is insufficient to support Reeves' recovery on three of the four theories submitted to the jury: defective manufacturing, defective design, and the unreasonably dangerous per se doctrine. AcroMed further maintains that the MDAs preempt Reeves' failure-to-warn claim.

II.

[1] [2] When a district court submits two or more alternative grounds for recovery to the jury on a single interrogatory and the plaintiff prevails, we ordinarily order a new trial if one of the grounds for recovery is "legally inadequate." *Walther v. Lone Star Gas Co.*, 952 F.2d 119, 126 (5th Cir.1992); **303 Pan Eastern Exploration v. Hufo Oils*, 855 F.2d 1106, 1123 (5th Cir. 1988). In such a case, "the reviewing court cannot determine whether the jury based its verdict on a sound or unsound theory." *Pan Eastern Exploration*, 855 F.2d at 1123; *Hayes v. Solomon*, 597 F.2d 958, 985 (5th Cir.1979) (holding that "the very real likelihood that the jury may have utilized an unproven or improper theory of liability to reach its verdict mandates reversal"). In the present case, the district court submitted four of Reeves' theories of recovery under the first interrogatory. The first interrogatory inquires whether AcroMed's product was "unreasonably dangerous as a spinal implant." The court instructed the jury that proof of one or more of Reeves' four theories of recovery was sufficient for an affirmative answer to the first interrogatory. Thus, if the court erroneously submitted one of the legal theories of recovery to the jury and the form of the interrogatory prevents us from determining upon which theory the jury based its verdict, we must vacate the judgment. *Hufo*, 855 F.2d at 1123.

AcroMed's primary contention on appeal is that the district court erroneously submitted Reeves' failure-to-warn theory of recovery to the jury. According to AcroMed, Reeves' failure-

to-warn claim is legally inadequate because it is preempted by the MDAs. We now turn to the merits of AcroMed's preemption argument.

III.

A.

Reeves produced evidence at trial that AcroMed failed to warn her or her doctor that its metal bone implant was not FDA approved for use in the spine. This evidence is the basis of her failure-to-warn claim.

The MDAs establish two separate approval processes for medical devices: Pre-Market Approval and Pre-Market Notification. The FDA's Pre-Market Approval process applies to new medical devices introduced after May 28, 1976, the date the MDAs were enacted. This process is lengthy and involves extensive investigation by the FDA. The FDA's Pre-Market Approval application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require Pre-Market Approval applicants to submit "[c]opies of all proposed labeling for the device." 21 C.F.R. § 814.20(b)(10). The FDA approves a Pre-Market Approval application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.

In contrast to the FDA's Pre-Market Approval process, the agency's Pre-Market Notification process is more abbreviated and involves less FDA oversight. To obtain FDA approval under this procedure, the applicant must demonstrate that its device is "substantially equivalent" to a device on the market prior to May 28, 1976. 21 C.F.R. § 807.87. The Pre-Market Notification process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. As with the Pre-Market Approval process, Pre-Market Notification applicants must also submit their proposed labeling. Id. If the

FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDAs in 1976, the applicant is free to market the device.

Reeves produced evidence that AcroMed applied twice to the FDA for approval to market its device as a spinal implant under the FDA's Pre-Market Notification process, and that the FDA rejected both applications. The FDA concluded that the implant was not substantially equivalent to any spinal implant on the market before 1976, and directed AcroMed to obtain additional animal and human data showing that the implant is safe and effective if used as a spinal implant. In December 1985, AcroMed submitted a third Pre-Market Notification application to the FDA covering the same implant, but omitting any statements identifying the spine as one of the potential uses of the device. In contrast to AcroMed's prior applications, this application stated that AcroMed intended to *304 market its implant for use in "appropriate fractures of long bones of both the upper and lower extremity," and other flat bones. The FDA approved AcroMed's implant for marketing based on the revised application.[2]

B.

[3] AcroMed contends that the MDAs expressly preempt Reeves' failure-to-warn claim. Section 360k(a) of the Act provides:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to this device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

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2. In January 1986, the FDA approved an additional AcroMed application for an investigational study allowing AcroMed to implant its device in the spines of a select group of patients under strict guidelines established by the FDA. Reeves was never a participant in such an investigational study.

21 U.S.C. § 360k(a) (emphasis added). AcroMed argues that § 360k(a) preempts Reeves' failure-to-warn claim because her claim, if successful, would impose a labeling requirement that is "in addition" to the FDA's labeling regulations.

The touch-stone of preemption analysis is Congressional intent. *Cipollone v. Liggett*, _____ U.S. _____, _____, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992). Congressional intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." Id. (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977)). Where Congress enacts legislation that specifically addresses the issue of preemption, the express language of the statute provides a "reliable indicium of congressional intent with respect to state authority." Id. at _____, 112 S.Ct. at 2618 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505, 98 S.Ct. 1185, 1190, 55 L.Ed.2d 443 (1978)). Consequently, the existence of an express preemption provision renders it unnecessary for us "to infer congressional intent to preempt state laws from the substantive provisions" of the MDAs. Id. Rather, to determine the precise boundaries of § 360k(a) "we need only identify the domain expressly preempted" by the language of the statute. Id.

We have previously held that § 360k(a) of the Act preempts common law failure-to-warn claims involving medical devices subject to the MDAs. In *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-247 (5th Cir.1989), the court held that § 360k(a) preempted a claim alleging that a tampon manufacturer had failed to provide adequate warnings concerning the dangers of toxic shock syndrome. The court based its decision primarily on the fact that FDA regulations specifically prescribe the form and content of toxic shock warnings on tampons. Id. Because the plaintiff's claim would essentially impose labeling requirements beyond those required by the FDA's regulations, the court concluded that § 360k(a) preempted the plaintiff's claim.

In *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423-24 (5th Cir.), *cert. denied* _____ U.S. _____, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), this court applied the reasoning of Moore to hold that preemption barred a failure-to-warn claim brought against

the manufacturer of an anti-wrinkle treatment. We reached this conclusion even though the FDA had not promulgated regulations that specifically prescribed the form and content of the product's labeling and warnings. The court reasoned that the FDA's Pre-Market Approval process requires agency review and approval of a device manufacturer's proposed labeling before a medical device can be marketed. Id. FDA approval of a device for marketing, therefore, signifies the agency's determination that the manufacturer's labeling is sufficient. Because common law failure-to-warn claims would impose labeling requirements beyond those required by the FDA, the court concluded that § 360k(a) preempted the plaintiff's failure-to-warn claim. Id.

C.

We conclude that the reasoning of *Moore* and *Stamps* applies to the present case because *305 Reeves' failure-to-warn-claim, if successful, would impose labeling requirements "in addition" to the requirements of the MDAs and FDA regulations. 21 U.S.C. § 360k(a). FDA regulations require device manufacturers to submit the proposed labeling and warnings for their devices to the FDA as part of the approval process under the MDAs. 21 C.F.R. § 807.87(e). FDA labeling regulations specifically require labels to disclose a device's uses, hazards, side effects, and any applicable precautions. 21 C.F.R. § 801.109. Based on its review of the manufacturer's proposed labeling, the agency can impose additional labeling requirements if it determines that "substantial deception" or unreasonable health danger could be corrected by "labeling or a change in labeling." 21 C.F.R. § 895.25. The FDA thus implicitly approves a manufacturer's proposed labeling when the agency approves a device for marketing. *Stamps*, 984 F. 2d at 1123. Because Reeves' failure-to-warn claim would impose labeling requirements beyond those required by the FDA, her claim runs afoul of § 360k(a) of the MDAs. Id.; see also 21 C.F.R. § 808.1(d)(6) (the MDAs preempt state requirements that have "the effect of establishing a substantive requirement for a specific device.")

Reeves attempts to distinguish this case from *Moore* and *Stamps* on three grounds. Reeves first argues that we should not give preemptive effect to the FDA's approval of AcroMed's labeling because the FDA approval process involved in this case is considerably less stringent than the review processes involved in *Stamps*. The anti-wrinkle treatment in *Stamps* was approved through the FDA's Pre-Market Approval process. In contrast, AcroMed's implant was approved through the FDA's Pre-Market Notification process. *Stamps*, 984 F.2d at 123. In support of her argument, Reeves points out that the FDA's approval of a device under the Pre-Market Notification process "does not in any way denote official approval of the device." 21 C.F.R. § 807.97.

[4] Reeves' attempt to distinguish this case on the basis of the type of FDA approval process at issue is unpersuasive. The FDA labeling requirements that prompted this court to apply preemption in *Stamps* also apply to products approved under the FDA's Pre-Market Notification process. Even if the FDA's Pre-Market Notification process does not result in the FDA's "official approval" of a device, the agency subjects the manufacturer's proposed labeling to extensive scrutiny. As discussed above, FDA regulations required AcroMed to submit its proposed labeling with its Pre-Market Notification application. See 21 C.F.R. § 807.87(e). The regulations also required the FDA to review AcroMed's labeling to ensure that it was in compliance with the general labeling regulations set out in 21 C.F.R. §§ 801 et seq. Therefore, despite the differences between the FDA's Pre-Market Approval and Pre-Market Notification procedures, our preemption analysis remains the same. The First Circuit used this same reasoning in holding that the preemptive effect of FDA labeling regulations apply equally to devices approved under the FDA's Pre-Market Approval and Pre-Market Notification procedures. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 17-18 (1st Cir.1994).

[5] Reeves also contends that preemption should not apply in this case because the AcroMed implant was used in the spine—an "off-label" use—rather than in the long bones of the upper or lower extremities, as stated in AcroMed's December 1985 application to the FDA. But, Reeves' attempt to distin-

guish this case based on the off-label use of AcroMed's implant is also flawed. FDA labeling regulations specifically address off-label uses of medical devices. For example, FDA regulations require manufacturers to provide appropriate labeling if the manufacturer has reason to believe that its medical device might be used for purposes different from the purposes for which the device is approved. 21 C.F.R. § 801.4.[3] Similarly, the FDA can require a manufacturer to provide *306 additional labeling that addresses potential off-label uses. 21 C.F.R. § 895.25. Consequently, the fact that Acro-Med's implant might have been used for an off-brand purpose is not sufficient to distinguish this case from *Moore* and *Stamps*.

[6] Finally, Reeves argues that preemption should not apply in this case because AcroMed misled the FDA and violated FDA regulations by withholding material information from the FDA concerning the intended uses of its product. Reeves argues that AcroMed failed to inform the FDA that they intended to market their device as a spinal implant. In support of this argument, Reeves produced evidence that AcroMed removed all references to spinal uses from its December 1985 Pre-Market Notification application to gain FDA approval after the FDA had rejected two prior applications to market the device as a spinal implant.

Reeves essentially invites us to create an exception to preemption under § 360k(a) in cases where a manufacturer withholds material information from the FDA during the approval process. Whether such an exception is warranted in a case involving a medical device subject to the MDAs is a question of first impression in this circuit. In *Hurley v. Lederle Lab. Div. of American Cyanamid Co.*, 863 F.2d 1173, 1179-1180 (5th Cir.1988) we declined to preempt a failure-to-warn claim

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3. According to § 801.4:

[I]f a manufacturer knows, or has knowledge of facts that would give it notice that a device introduced into interstate commerce by a manufacturer is to be used for conditions, or uses other than the ones for which he offers it, he is required to provide adequate labeling . . . which accords with such other uses to which the article is to be put.

brought against a vaccine manufacturer. We based our holding on the plaintiff's allegations that the manufacturer withheld material information from the FDA during the vaccine's approval process.

Our holding in Hurley however is distinguishable from the present case. In contrast to the present case, Hurley did not involve a medical device subject to approval under the MDAs. More importantly, because the vaccine at issue in Hurley was not subject to the express statutory preemption provision in § 360k(a) of the MDAs, we based our analysis on implied preemption principles. As the Supreme Court made clear in *Cipollone*, implied preemption analysis is inapplicable where a statute contains an express preemption provision. Therefore, the focus of our preemption analysis must be the language of § 360k(a). _____ U.S. at _____, 112 S.Ct. at 2618.

Only one other circuit has specifically addressed whether evidence of fraud on the FDA is sufficient to defeat preemption under § 360k(a) of the MDAs. In *King v. Collagen Corp.*, 983 F.2d 1130, 1139-1140 (1st Cir.1993), the First Circuit declined to create an exception to preemption under the MDAs where the plaintiff alleged that the manufacturer fraudulently withheld material safety information from the FDA during the approval process. The court reasoned that the FDA was in the best position to determine whether a manufacturer has withheld material information.

> [W]here the FDA was authorized to render the expert decision on *Collagen*'s use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions.

Id. at 1140. The court also observed that an erroneous jury finding that a manufacturer failed to disclose material information would be tantamount to imposing a requirement "that is different from, or in addition to, any requirement applicable . . . to the device." Id. (quoting 21 U.S.C. § 360k(a)). The court concluded, therefore, that a fraud-on-the-FDA exception to preemption would inevitably run afoul of the MDA's express preemption provision in § 360k(a). See also *Papas v. Upjohn Co.*, 985 F.2d 516, 518-519 (11th Cir.1993) (declining to find an ex-

ception to an express preemption provision under the Federal Insecticide, Fungicide, and Rodenticide Act based on allegations that a pesticide manufacturer withheld material information from the Environmental Protection Agency).

Other courts have declined to create an exception to preemption under the MDAs in cases where manufacturers allegedly violated FDA labeling regulations. In *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 993-94 (8th Cir.1994), the Eighth Circuit held that the plaintiff's failure-to-warn claim was preempted under § 360k(a) even though the plaintiff alleged that the defendant manufacturer had violated FDA labeling regulations. The court reasoned that the MDAs require the *307 FDA to determine whether a manufacturer's proposed labeling complies with FDA labeling regulations when the agency approves a device for marketing. Accordingly, permitting a state law failure-to-warn claim based on allegations that a manufacturer violated FDA labeling regulations would essentially constitute a collateral attack on the FDA's original determination that the manufacturer was in compliance with all applicable regulations. Id. The court concluded that such an attack on the FDA's determination of compliance is preempted by § 360k(a).[4]

We agree with the reasoning of *King* and *El Dorado* and, therefore, decline Reeves' invitation to create an unwieldy exception to *Moore* and *Stamps* in cases where manufacturers attempt to mislead the FDA or violate FDA regulations. The MDAs establish an extensive enforcement scheme under which the FDA bears the primary responsibility for policing violations

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4. Other courts have questioned the applicability of preemption in cases where a manufacturer has violated FDA regulations. However, most of the statements favoring an exception to preemption under these circumstances are in dicta. See *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir.1992) (Posner, J.) (reasoning that preemption under § 360k(a) "is limited to efforts by states to impose sanctions for compliance with federal regulations"); see also *Tarallo v. Searle Pharmaceutical, Inc.*, 704 F.Supp. 653, 655 (D.S.C.1988). However, as of the date of this opinion, no court has squarely held that a violation of FDA labeling regulations defeats preemption of state failure-to-warn claims.

of its regulations. *El Dorado*, 38 F.3d at 994. In fact, the MDAs specifically proscribe the submission of fraudulent forms to the FDA and establish civil and criminal penalties for intentionally defrauding or misleading the FDA. See 21 U.S.C. §§ 331, 333(a)(2), 333(g); see also *United States v. Arlen*, 947 F.2d 139, 142-43 (5th Cir.1991).[5] Given the FDA's central role in reviewing and approving devices under the MDAs, the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction. Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers. See H.R. Report No. 853, 94th Cong., 2d Sess. 9 (1976) (explaining that the principal purpose of § 360k(a) is to eliminate conflicting regulations). For these reasons, we conclude that § 360k(a) of the MDAs preempts Reeves' failure-to-warn claim.

IV.

We conclude, therefore, that the district court erred in submitting Reeves' failure-to-warn theory of recovery to the jury. Because we cannot determine whether the jury based its affirmative answer to Interrogatory One on Reeves' legally inadequate failure-to-warn theory of recovery, we must vacate

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5. 21 U.S.C. § 331 states:

The following acts and the causing thereof are prohibited:

• • • • •

(q)(2) With respect to any device, the submission of any report that is required by or under this chapter that is false and misleading in any material respect.

21 U.S.C. § 333(a) establishes criminal penalties for violations of § 331:

(a)(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person . . . commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

the district court's judgment and remand the case for retrial. The only remaining issue is which of the three remaining theories of recovery the district court must retry on remand.

AcroMed contends that Reeves failed to introduce sufficient evidence to recover on the basis of a design or manufacturing defect. We have carefully reviewed the record and find no evidence to support a recovery on the basis of a defect in the fabrication or manufacture of AcroMed's implant. On appeal, *308 Reeves points to no evidence that would support a recovery on this theory. Consequently, there is insufficient evidence to retry this theory of recovery on remand.

[7] Reeves also failed to establish all the elements required by Louisiana law to recover on a defective design theory. To prevail on this theory, Louisiana law requires a plaintiff to establish the existence of an alternative safer design for the product. *Halphen v. Johns-Manville Sales Corp.*, 484 So.2d 110, 115 (La.1986). Reeves introduced no evidence of an alternative safer design. Indeed, she does not argue on appeal that she satisfied this requirement.

[8][9][10] Finally, AcroMed contends that Reeves failed to produce sufficient evidence at trial to support her recovery under the theory that AcroMed's implant is unreasonably dangerous per se. A product is unreasonably dangerous per se if "[a] reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product." *Halphen*, 484 So.2d at 115. While this theory of recovery eliminates the "state of the art" defense, the plaintiff is not relieved of the burden of proving that the product is defective. *Valenti v. Surgiteck-Flash Medical Eng. Corp.*, 875 F.2d 466, 468 (5th Cir.1989). Thus, in order to carry her burden, Reeves must establish that some inherent characteristic of AcroMed's implant renders it unreasonably dangerous for use in the spine.

We conclude that Reeves' evidence is sufficient to support submitting her unreasonably dangerous per se claim to the jury. In support of her claim, Reeves points to an October 1985 FDA letter rejecting AcroMed's original application to have its implant approved as a spinal implant. In this letter, the FDA cites several potential health hazards of AcroMed's device as a

spinal implant. The FDA specifically referred to its concern about the stability of the device and that the screws could break and damage the bones in the spine. This evidence, together with evidence that allowed the jury to infer that the screws broke and exacerbated Reeves' back pain, is sufficient to create a jury issue. We conclude, therefore, that there is sufficient evidence to retry Reeves' unreasonably dangerous per se theory of recovery on remand.

V.

For the reasons stated above, we must VACATE the judgment and REMAND this case for retrial of Reeves' unreasonably dangerous per se theory of recovery. *Pan Eastern Exploration*, 855 F.2d at 1123.

VACATED and REMANDED.

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 93-3752

DOROTHY MARIE REEVES,
Plaintiff-Appellee,

v.

ACROMED CORPORATION, ET AL.,
Defendants,

ACROMED CORPORATION and
ST. PAUL FIRE AND MARINE
INSURANCE COMPANY,
Defendants-Appellants.

Appeal from the United States District Court
for the Eastern District of Louisiana

ON PETITION FOR REHEARING
(April 3, 1995)

Before JOHNSON, HIGGINBOTHAM and DAVIS, Circuit Judges.
PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above case is denied.

ENTERED FOR THE COURT:

United States Circuit Judge

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 808.1

§ 808.1 Scope.

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 8, 1976, no

State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of

State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local

requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating

to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

21 C.F.R. § 807.87

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commer-

cial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

21 C.F.R. § 801.109

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device,

and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1) (i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however*, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to

omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

21 C.F.R. § 895.25

§ 895.25 Labeling.

(a) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device specifying:

(1) The deception or risk of illness or injury or the danger to the health of individuals,

(2) The labeling or change in labeling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and

(3) The period of time within which the labeling, change in labeling, or change in advertising must be accomplished.

(b) In specifying the labeling or change in labeling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to include in labeling for the device, and in advertising if the device is a restricted device, a statement, notice, or warning. Such statement, notice, or warning shall be in the manner and form prescribed by the Commissioner and shall identify the deception or risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals associated with the device as previously labeled. Such statement, notice, or warning shall be used in the labeling and advertising of the device for a time period specified by the Commissioner on the basis of the degree of deception, risk of illness or injury, or danger to health; the frequency of sale of the device; the length of time the device has been on the market; the intended uses of the device; the method of its use; and any other factors that the Commissioner considers pertinent.

(c) The Commissioner will allow a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device a reasonable time, considering the deception or risk of illness or injury or the danger to the health of individuals presented by the device, within which to accomplish the required labeling, change in labeling, and, if the device is a restricted device, any change in advertising. The Commissioner may, however, request that no additional devices be introduced into commerce until the labeling or change in labeling, or change in advertising is accomplished by the manufacturer, distributor, importer, or other person(s) responsible for the labeling or advertising of the device.

(d) If such voluntary action is not taken, the Commissioner may take action under other sections of the act to prevent the introduction of the devices into commerce. The Commissioner may consider the failure of a manufacturer, distributor,

importer, or any other person(s) responsible for the labeling or advertising of the device to accomplish the required labeling or change in labeling, or change in advertising in accordance with this section as a basis for initiating a proceeding to make a device a banned device in accordance with § 895.21(d) and when appropriate to establish a special effective date in accordance with § 895.30.